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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

FRANK MORGAN and JANET HOOD, individually and on behalf of all others similarly situated, Plaintiffs, vs. WALLABY YOGURT COMPANY, INC., Defendant.		No. CV 13-00296-JD **REPLY IN SUPPORT OF WALLABY'S MOTION FOR RECONSIDERATION IN LIGHT OF NEW AUTHORITY** Hearing Date: September 17, 2014 Time: 9:30 a.m. Courtroom: 11 – 19th Floor Judge: Hon. James Donato Action Filed: January 22, 2013

INTRODUCTION

In their opposition brief, Plaintiffs ask this Court to part ways and disagree with Judge Richard Seeborg, Judge Susan Illston, Judge Thelton Henderson, Judge Saundra Armstrong, Judge Yvonne Gonzales Rogers, Judge Edward Chen, Judge Edward Davila, Judge Vince Chhabria, Judge Janis Sammartino, and Judge Elizabeth LaPorte. All of these judges have dismissed or stayed evaporated cane juice lawsuits in light of the FDA's March 5, 2014 announcement that it was backing away from its 2009 Draft Guidance on "evaporated cane juice."

The tide has turned so much that even Judge Orrick — who had previously declined to invoke the primary jurisdiction in this case before it was reassigned — recently changed his mind and stayed a different evaporated cane juice lawsuit. Indeed, since Wallaby's motion for reconsideration was filed, three additional judges have invoked the primary jurisdiction doctrine in evaporated cane juice cases.

The result should be no different here. Under the primary jurisdiction doctrine, a court has the option of deferring an issue to an agency if it would promote the uniform application of laws and allow an agency that has expertise and responsibility over that issue to resolve it. Here, the FDA has jurisdiction over food labeling, and has commenced a formal regulatory process to determine whether it is permissible to describe the ingredient at issue as "evaporated cane juice." It makes little sense for this Court to address the very issue that is under review by the FDA, thereby risking potential conflict and undermining the regulatory process. Plaintiffs' arguments in their opposition brief are either red herrings or have already been rejected in the over dozen opinions dismissing or staying evaporated cane juice claims.

ARGUMENT

I. This Court Already Granted Wallaby Leave to Seek Reconsideration Under L.R. 7-9.

Recognizing the strength of Wallaby's request on the merits, Plaintiffs first argue that the reconsideration motion is procedurally deficient under Local Rule 7-9. This argument is a red herring. While Civil Local Rule 7-9 requires a party to obtain permission to seek reconsideration, this Court *already* "grant[ed] defendant's request to seek reconsideration of the potential application of the primary jurisdiction doctrine," directing Wallaby to file its "reconsideration motion . . . as a regularly noticed motion." ECF No. 62. Plaintiffs' argument is therefore untimely and irrelevant.

II. Judge Orrick Recently Reversed His Prior Reasoning and Stayed a Similar ECJ Case, As Did Two Additional Judges Since the Filing of Wallaby's Motion for Reconsideration.

In Wallaby's motion for reconsideration, Wallaby pointed out that over a dozen decisions have held that ECJ claims should be dismissed or stayed under the primary jurisdiction doctrine. In the face of this overwhelming authority, Plaintiffs resorted to relying heavily on Judge Orrick's prior decisions (in both *Wallaby* and *Amazon Preservation*) declining to invoke the primary jurisdiction doctrine.

But the day before Plaintiffs filed their opposition brief, Judge Orrick reversed course and stayed an evaporated cane juice case. *See Swearingen v. Amazon Preservation Partners, Inc.*, No. 13-4402, 2014 WL 3934000, at *2 (N.D. Cal. Aug. 11, 2014). Like in *Wallaby*, Judge Orrick had initially refused to revisit his prior opinion declining to invoke the primary jurisdiction doctrine. *See Swearingen v. Amazon Preservation Partners, Inc.*, No. 13-4402, 2014 WL 1100944, at *4 n.3 (N.D. Cal. Mar. 18, 2014). But on August 11, Judge Orrick reconsidered and ruled that the ECJ claim should be stayed, noting (among other things) that "several of my colleagues in this Court have stayed similar pending food labeling cases regarding the term 'evaporated cane juice.'" 2014 WL 3934000, at *2. In short, Judge Orrick, like the majority of other judges in this District, "find[s] it appropriate to stay this case under the primary jurisdiction doctrine in light of the FDA's March 5, 2014 notice." *Id.*

Judge Chhabria of the Northern District and Judge Sammartino of the Southern District also recently joined the overwhelming chorus of judges invoking the primary jurisdiction doctrine in cases involving evaporated cane juice claims.

On August 8, 2014, Judge Chhabria concluded in *Gitson v. Trader Joe's Co.* that "it makes sense to stay the plaintiffs' evaporated cane juice claims to see if the [FDA] does, in fact, issue final guidance on the issue." --- F. Supp. 2d ----, 2014 WL 3933921, at *2 (N.D. Cal. 2014).

Three days later, Judge Sammartino of the Southern District of California reached a similar conclusion, dismissing the *Saubers v. Kashi Co.* matter because "[a]llowing the FDA to resolve this matter in the first instance would permit the Court to benefit from the agency's technical expertise and would also provide for uniformity in administration of the agency's food labeling requirements." --- F. Supp. 2d ----, 2014 WL 3908595, at *3 (S.D. Cal. 2014).

III. The *Pom Wonderful* Opinion, Which Addressed Lanham Act Claims, is Irrelevant Here.

Plaintiffs argue that the dozen-plus cases rejecting their arguments are invalid because of the Supreme Court's *POM Wonderful* opinion. But as Judge Sammartino recently explained, *POM Wonderful* "is inapposite . . . because *POM Wonderful* makes no mention of the primary jurisdiction doctrine and stands principally for the proposition that Lanham Act unfair competition claims brought by a competitor are not *precluded* by the regulatory scheme of the federal Food, Drug, and Cosmetic Act." *Saubers*, 2014 WL 3908595, at *4 (emphasis in original).

Moreover, *POM Wonderful* involved two competing federal statutes — the Lanham Act and the Food, Drug, and Cosmetic Act — which does not implicate the Supremacy Clause that undergirds preemption. Accordingly, *POM Wonderful* was a "preclusion case" rather than a "pre-emption case" in which "the state-federal balance" implicated by state-law consumer fraud claims did "not frame the inquiry." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014) (the Supreme Court explicitly noting that its decision is not a federal preemption case involving a state law claim).[1] In short, the Supreme Court's ruling regarding preclusion in a Lanham Act competitor case has no bearing on this Court's primary jurisdiction analysis.[2]

IV. Plaintiffs' Remaining Arguments are Equally Flawed and Have Been Repeatedly Rejected.

Plaintiffs oppose invocation of the primary jurisdiction doctrine by repeating the same arguments that have already been repeatedly rejected by judges in this District. They are no more persuasive here.

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[1] *See POM Wonderful*, 134 S. Ct. at 2238 (explaining that the FDCA's preemption provision forbids "*state-law* requirements that are of the type but not identical to . . . certain FDCA provisions with respect to food and beverage labeling" but "does not refer to . . . federal statutes" such as the Lanham Act) (emphasis added); *id.* at 2239-40 (characterizing the acceptable "variation in outcome" that could arise from application of a federal statute by courts around the country as "quite different" from the "disuniformity" that would arise from allowing state laws to impose standards that differ from the FDA's rules and regulations).

[2] Although the *Ibrarrola* court briefly mentioned *POM Wonderful*, the parties did not have the opportunity to brief the relevance of that case, and the court ultimately "refrain[ed] from substantively considering" the primary jurisdiction doctrine, which was unnecessary because the Court had already concluded that the plaintiff's claims were subject to dismissal on the merits. *See Ibarrola v. Kind, LLC*, No. 13-50377, 2014 WL 3509790, at *4-6 (N.D. Ill. July 14, 2014).

First, Plaintiffs assert that the FDA has a long-established position regarding the common or usual name for evaporated cane juice, relying on the 2009 Draft Guidance. But they ignore that the FDA has backed away from its 2009 Draft Guidance. Furthermore, the 2009 Draft Guidance itself makes clear that it is "for comment purposes only," "not for implementation," does "not operate to bind FDA or the public," and will represent the FDA's "current thinking" only "when finalized." 2009 WL 3288507; 74 Fed. Reg. 51610-01. As one court put it, "these words of caution indicate that the FDA, the entity charged with creating and maintaining a uniform scheme of non-misleading food labels, was in the process of formulating a final position on the propriety of using the ingredient term ECJ in food labeling." *Figy v. Lifeway Foods*, No. 13-4828, 2014 WL 1779251, at *3 (N.D. Cal. May 5, 2014). In other words, "it is apparent from the face of the 2009 Draft Guidance that it only represents the FDA's preliminary view of the issue and not its formal position." *Figy v. Amy's Kitchen, Inc.*, No. 13-3816, 2014 WL 1379915, at *3 (N.D. Cal. Apr. 9, 2014); *see also Reese v. Odwalla, Inc.*, --- F. Supp. 2d ----, 2014 WL 1244940, at *5 (N.D. Cal. 2014) ("the FDA's position on the lawfulness of the . . . term is not only . . . 'not settled,' it is also under active consideration by the FDA"). Indeed, the March 5, 2014 FDA notice conclusively confirms that the FDA has "not reached a final decision on the common or usual name for this ingredient." 79 Fed Reg. 12507 (Mar. 5, 2014).

Second, Plaintiffs argue that the Court need not invoke the primary jurisdiction doctrine because "[t]his case does not involve a particularly complicated issue." This conclusory argument simply ignores the complex nature of the issue — and the holdings of the majority of judges in this District. As Judge Ilston explained: "As the March 5, 2014 notice states, consideration of whether ECJ is the common or usual name of the ingredient involves consideration of ECJ's method of production, the differences between ECJ and other sweeteners, and its basic characterizing properties. Resolution of these issues requires the expertise of the FDA." *Amy's Kitchen*, 2014 WL 1379915, at *3.[3]

[3] *See also Swearingen v. Yucatan Foods*, ---F. Supp.2d. ---, 2014 WL 2115790, at *2 (N.D. Cal. 2014) ("The question of evaporated cane juice labeling presents a host of technical issues uniquely within the [FDA's] expertise"); *Swearingen v. Late July Snacks LLC*, No. 13-4324, 2014 WL 2215878, at *3 (N.D. Cal. May 29, 2014) ("Resolution of this issue requires the FDA's expertise because it involves analysis of the method of manufacturing ECJ and whether that method differs from the manufacturing of sugar").

Third, Plaintiffs argue that the primary jurisdiction doctrine is inapplicable because any final guidance issued by the FDA is not entitled to deference to the extent it varies from the Draft Guidance. Opp. at 17 (arguing any such deference would "pull[] the rug out from under litigants that have relied on a long-established, prior interpretation of a regulation"). This argument fails for several reasons:

- As explained above, the Draft Guidance does not communicate the FDA's long-established position. "[T]here has never been a final interpretation of the regulations with regard to ECJ;" rather, "[t]he 2009 Draft ECJ Guidance was just that—a draft." *Gitson v. Clover Stornetta Farms*, No. 13-1517, 2014 WL 2638203, at *5 (N.D. Cal. June 9, 2014) (rejecting plaintiff's argument that the FDA's final guidance would not be binding because it is a change in position).
- Moreover, even if different from the draft, the FDA's final guidance cannot be seen as change in position. From the outset, the FDA made clear that "[a]fter reviewing the comments received, *we intend to revise the draft guidance, if appropriate, and issue it in final form*." 79 Fed. Reg. 12507, 12508 (emphasis added). Indeed, the FDA expressly stated that the 2009 Draft Guidance would reflect the FDA's position only after being finalized. 74 Fed. Reg. at 51610. Because the final guidance will be the FDA's first statement regarding its final position, it cannot constitute a "change" in the FDA's position. *See Clover Stornetta*, 2014 WL 2638203, at *5 (there is no showing that "a reopening of the comment period for an ingredient in advance of issuing final guidance as to that ingredient is 'inconsistent with previously held views'").
- Further, only an agency's actual, final interpretation of its regulations would be relevant. Even the principles on which Plaintiffs rely apply only to an agency's actual "interpretation of its own regulation," and would include such interpretation even if it is made "through an informal process." *Public Lands for the People, Inc. v. U.S. Dep't of Agric.*, 697 F.3d 1192, 1199 (9th Cir. 2012). The Draft Guidance is not the FDA's actual interpretation on the subject and is not entitled to deference under *Auer v. Robbins*, 519 U.S. 452 (1997). In contrast, there can be no doubt that the FDA's final interpretation of whether "evaporated cane juice" complies with the "common or usual name" requirement should be considered.

- Finally, allowing Plaintiffs' state-law claims to interrupt the FDA's regulatory process would be unfairly prejudicial. The FDA's process — and the 2009 Draft Guidance itself — make it abundantly clear that the food and beverage companies were *not* required to take action in response to the Draft Guidance. These companies thus acted appropriately in monitoring the FDA's process and in being prepared to respond after the FDA issued final guidance. It was particularly reasonable to await final guidance, given the many comments submitted to the FDA in 2009 disagreeing with the Draft Guidance. *See, e.g.*, RJN Exs. 2, 4. Ignoring the FDA's regulatory process and any final guidance would pull the rug out from those companies that relied on the FDA's process.

Fourth, Plaintiffs maintain that, irrespective of what the FDA ultimately decides on evaporated cane juice, that term is inaccurate because they claim that federal regulations require the word "sugar" to be used because of its sucrose content. Plaintiffs misread 21 C.F.R. § 101.4(b)(20), which merely defines "sugar" as "sucrose, which is obtained from sugar cane or sugar beets." Put another way, FDA regulations dictate that when the term "sugar" is included in an ingredient list, that term means "sucrose." *Id.* Critically, however, this does *not* mean that *all* ingredients "obtained from sugar cane or sugar beets" *must* be described in the ingredient list as "sugar." Even in the 2009 Draft Guidance, the FDA did not insist that "evaporated cane juice" must be described as "sugar"; the suggested term in that Draft Guidance was "evaporated cane syrup." In fact, Plaintiffs implicitly admit that their "sugar" argument is off-base because they recognize that molasses and cane sirup — both of which are obtained from sugar cane — are properly described as "molasses" and "cane sirup," not "sugar." *See* FAC ¶ 41.

Fifth, Plaintiffs argue against application of the primary jurisdiction doctrine on the ground that this is a "suit for violations of California's Sherman Law, which has its own common or usual name requirement that is independent of the FDCA or any incorporated regulations." Opp. at 18. The crux of Plaintiffs' argument is that the Sherman Law is consistent with the FDCA and their claims are consistent with what they (incorrectly) view as the FDA's "current interpretation of those regulations" (*i.e.*, the Draft Guidance). *Id.* So, they argue, "[t]o the extent the FDA might alter" its interpretation of the common or usual name requirement "in the future, neither it, nor federal courts can preclude California from enforcing its own laws as they are currently worded and interpreted." *Id.*

This argument is flawed for two reasons. As a preliminary matter, it continues to rely on Plaintiffs' incorrect conclusion that the FDA has put forth an interpretation of the common or usual name requirement as to evaporated cane juice. To the contrary, however, "the FDA has not resolved the issue of whether ECJ is the common or usual name of the ingredient at issue." *Amy's Kitchen*, 2014 WL 1379915, at *3. Accordingly, the state-law requirements Plaintiffs seek to enforce are necessarily "not identical" to the requirements under the FDCA.

Plaintiffs' argument also ignores and misapplies the principles of federal preemption of state-law claims. The Nutritional Labeling & Education Act (NLEA) prohibits any state law that seeks to promulgate a "common or usual name" requirement "that is not identical to the [federal] requirement." 21 U.S.C. §§ 343-1(a)(2); 343(i)(2). Accordingly, as one judge in this District explained in considering the very same argument: "Plaintiffs' argument that its Sherman Law claims are unaffected by the FDA's actions on ECJ is puzzling; while it is true that Plaintiffs have state law rights that are distinct from their rights under federal law, the FDA is charged with governing food labels and *states must have identical requirements*." *Clover Stornetta*, 2014 WL 2638203, at *6 (emphasis added).

Finally, Plaintiffs' remaining arguments are based on wholesale speculation — *e.g.*, that the FDA may not ultimately revise the Draft Guidance in a material way, or that it may take a long time to do so. The benefits of awaiting the FDA's final guidance (regardless of what it may ultimately say), such as preservation of judicial and party resources and uniformity in application, far outweigh any of Plaintiffs' speculation. *See, e.g., Lifeway Foods*, 2014 WL 1779251, at *4 ("application of the primary jurisdiction doctrine with respect to the FDA's position on ECJ will enhance the Court's decision-making efficiency by allowing the Court to benefit from the FDA's definitive guidance on the issue and assure uniform application of regulatory law").

In sum, this Court should follow the overwhelming majority of courts to have considered this issue and conclude that the FDA's March 5 notice warrants application of the primary jurisdiction doctrine in this case.

V. The Court Should Dismiss Plaintiffs' Complaint Without Prejudice.

"Whether to stay or dismiss without prejudice a case within an administrative agency's primary jurisdiction is a decision within the discretion of the district court." *Davel Commc'ns, Inc. v. Qwest*

Corp., 460 F.3d 1075, 1091 (9th Cir. 2006). But "[n]ormally, if the court concludes that the dispute which forms the basis of the action is within the agency's primary jurisdiction, the case should be dismissed without prejudice." *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 782 (9th Cir. 2002).

Accordingly, several courts have dismissed "evaporated cane juice" claims without prejudice after concluding the primary jurisdiction doctrine was implicated. *See Yucatan Foods*, 2014 WL 2115790, at *2-3 (holding "no particular disadvantage inures to the plaintiffs" by dismissing suit with prejudice rather than issuing a stay); *Smedt v. Hain Celestial Grp., Inc.*, No. 12-3029, 2014 WL 2466881, at *4-5 (N.D. Cal. May 30, 2014) ("At this juncture, the Court must dismiss the ECJ claims based on the primary jurisdiction doctrine."); *Avila v. Redwood Hill Farm & Creamery, Inc.*, No. 13-335, 2014 WL 2090045, at *3 (N.D. Cal. May 19, 2014) (same); *Saubers*, 2014 WL 3908595, at *2, 4 (rejecting argument that stay was preferable because "dismissal would be improper and prejudicial," and concluding "the doctrine of primary jurisdiction counsels dismissal . . . without prejudice"); *Swearingen v. Attune Foods, Inc.*, No. 13-4541, 2014 WL 2094016, at *3 (N.D. Cal. May 19, 2014); *Hood v. Wholesoy & Co.*, No. 12-5550, 2013 WL 3553979, at *4, 6 (N.D. Cal. July 12, 2013).[4]

Courts in this District evaluating other types of labeling claims have also found it appropriate to dismiss those claims without prejudice under the primary jurisdiction doctrine. *See, e.g., Gordon v. Church & Dwight Co.*, No. 09-5585, 2010 WL 1341184, at *2 (N.D. Cal. Apr. 2, 2010) ("the action must be DISMISSED under the primary jurisdiction doctrine"); *Ivie v. Kraft Foods Global, Inc.*, No. 12-2554, 2013 WL 685372, at *7 (N.D. Cal. Feb. 25, 2013) ("The court dismisses plaintiff's state law claims based on 'one mint' serving size labels under the primary jurisdiction doctrine."); *Cox v. Gruma Corp.*, No. 12-6502, 2013 WL 3828800, at *2 (N.D. Cal. July 11, 2013) (dismissing case without prejudice with respect to the primary jurisdiction doctrine); *accord Clark v. Time Warner Cable*, 523 F.3d 1110, 1114-16 (9th Cir. 2008) (affirming dismissal with prejudice of fraud, fraudulent concealment and negligence claims, among others).

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[4] While Plaintiffs have pointed to two cases in which Judge Illston reversed her initial decision of dismissal in favor of a stay, the numerous other dismissal decisions remain in force.

Further, while a stay may be appropriate in certain situations, there is no indication those circumstances are present here. Again, Plaintiffs' arguments are purely speculative: depending on the language of the FDA's final guidance, further proceedings *may* be contemplated, and depending on the time that elapses, there *may* be a statute of limitations concern. Plaintiffs' first argument — that there may be further proceedings — is based on their misguided contention that the FDA "will likely stick with its longstanding position." Opp. at 21. As explained above, however, the FDA has never established a firm position, and there is no reason to assume the agency re-opened the comment period, seeking comments on specific questions, merely to reaffirm its 2009 Draft Guidance. In any event, this is precisely why any dismissal would be *without prejudice*: if Plaintiffs believe "further proceedings" are appropriate after the FDA issues its final guidance, they may re-file their complaint.

Plaintiffs next contend a stay would be preferable due to "potential limitations issues." They do not, however, provide any facts or evidence indicating there may be statute of limitations concerns. They do not, for example, identify *when* the named Plaintiffs purchased Wallaby products. Nor does Plaintiffs' speculation that the process may be lengthy render dismissal improper; "it is clear from the agency's recent notice that there is 'an active and ongoing regulatory process' involving the specific issues raised in this litigation," and the comment period closed months ago. *See Saubers*, 2014 WL 3908595, at *4 (rejecting plaintiffs' argument that "dismissal would be improper and prejudicial . . . because the FDA had not indicated the time frame within which it intends to complete its revisions"). Accordingly, there is no basis for concluding there exists a "risk" that the statute of limitations will run on Plaintiffs' claims. *See Davel*, 460 F.3d at 1091.

Indeed, Judge Seeborg refused to reconsider his dismissal ruling in a case that, like this one, seeks restitution under the UCL, holding "it was appropriate to exercise judicial discretion to dismiss rather than stay th[e] action, in light of the various considerations articulated by the Ninth Circuit in *Davel Communications*," including the statute of limitations. *Swearingen v. Yucatan Foods, L.P.*, No. 13-3544, ECF No. 46 at 2 (June 9, 2014); *see also All One God Faith, Inc. v. Hain Celestial Grp., Inc.*, No. 09-3517, 2012 WL 3257660, at *11 (N.D. Cal. Aug. 8, 2012) (finding dismissal appropriate where re-filed claim was unlikely to be found untimely in light of "plaintiff's vigorous opposition to the dismissal of th[e] case, and the emerging regulations in this area").

CONCLUSION

Wallaby respectfully submits that the FDA's March 5, 2014 Notice warrants reconsideration of the Court's prior rulings on primary jurisdiction grounds. Wallaby therefore requests that the Court dismiss Plaintiffs' claims without prejudice or, in the alternative, stay the case pending the issuance of final guidance from the FDA.

Dated: September 3, 2014

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